

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



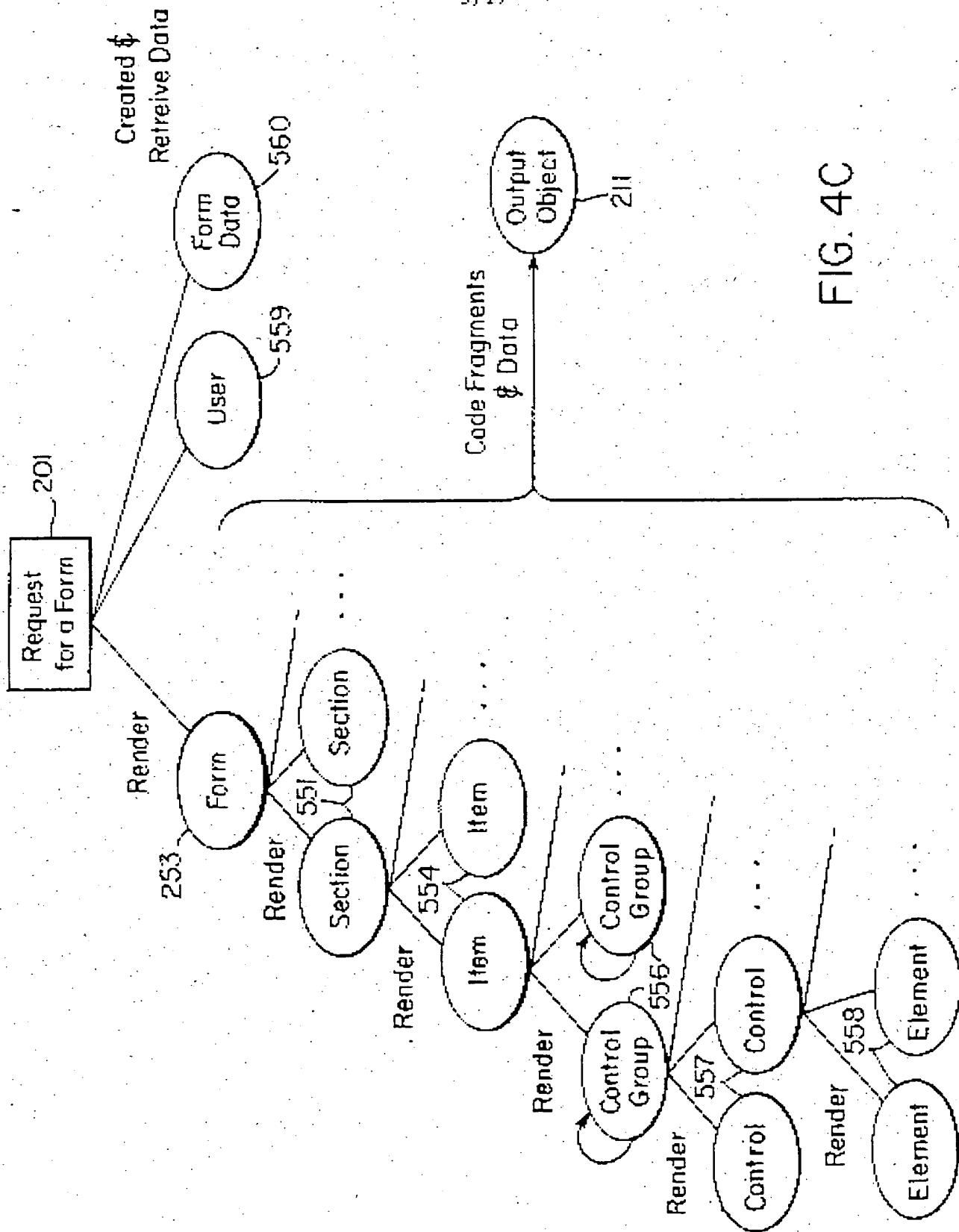


FIG. 4C

219

6/17

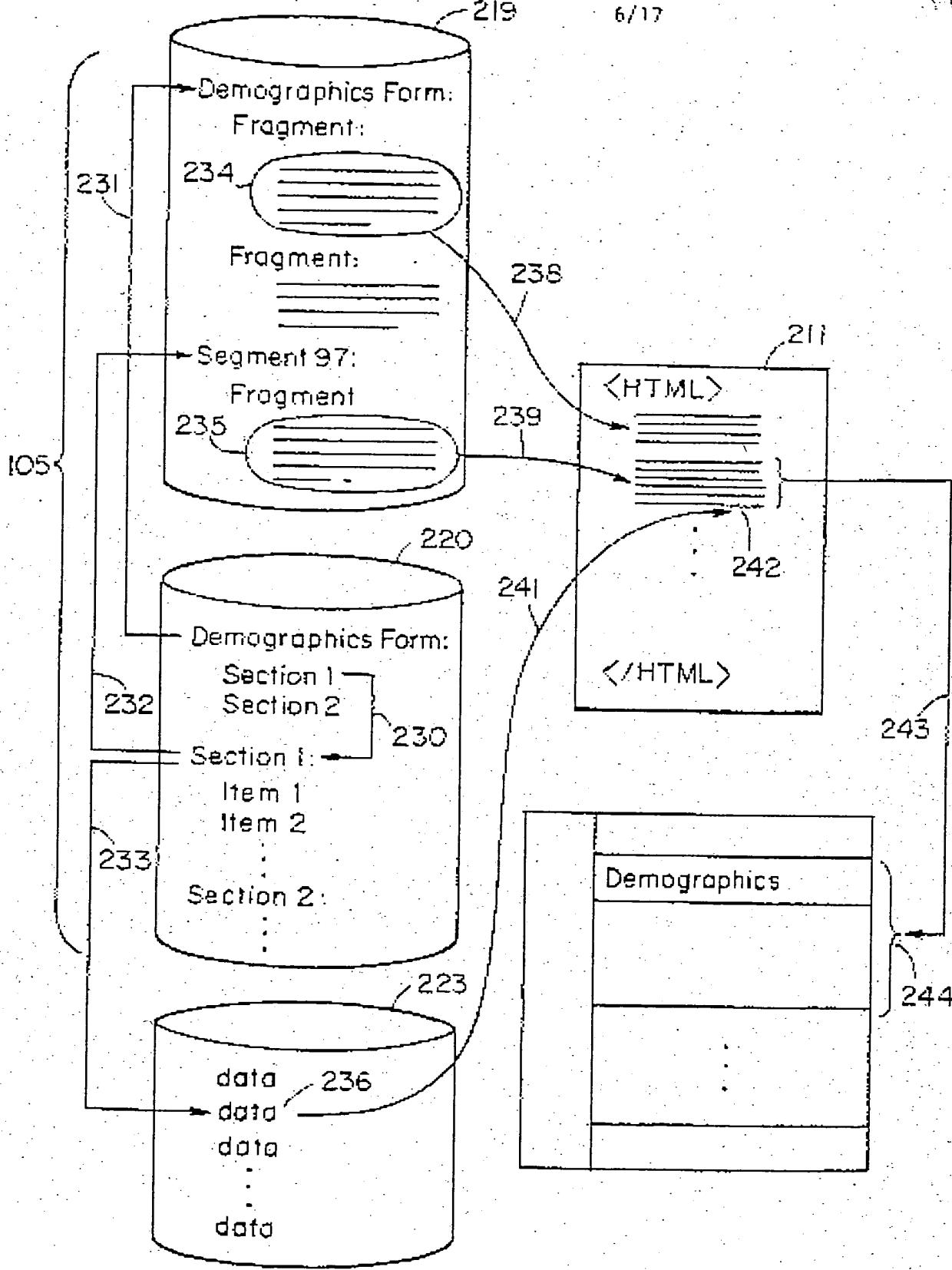


FIG. 4D

7/17
275

251B

277

	Week 4 Week 2 Week 1 Week 2 Week 3 Week 5 Weeks Week 7 Week 8
	IF DEM HH BS PE (VS/BP) (ECG/CR) LAB CM
John E Raymond Laboratory Assistants	Ready for SDV Patient: JPK Patient No: CH-DCI
Demographics	
1. Gender	Female
2. Date of Birth	Feb 19, 1954
3. Race/Ethnic Origin	Black
4. Height:	66 in
5. Weight:	145 lb
6. Frame:	Medium
Calculated weight variance from avg.	
Smoking History	
7. Has patient ever smoked?	No
You indicate that the patient smokes cigarettes in item 8. Please check that one of the correct answers to this 'Has the patient ever smoked?'	
B. If the patient has ever smoked, has the patient quit smoking?	No
C. If the patient currently smokes, the patient smokes:	Cigarettes
D. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day:	1
Next Reverse Exit	

251A

251C

291

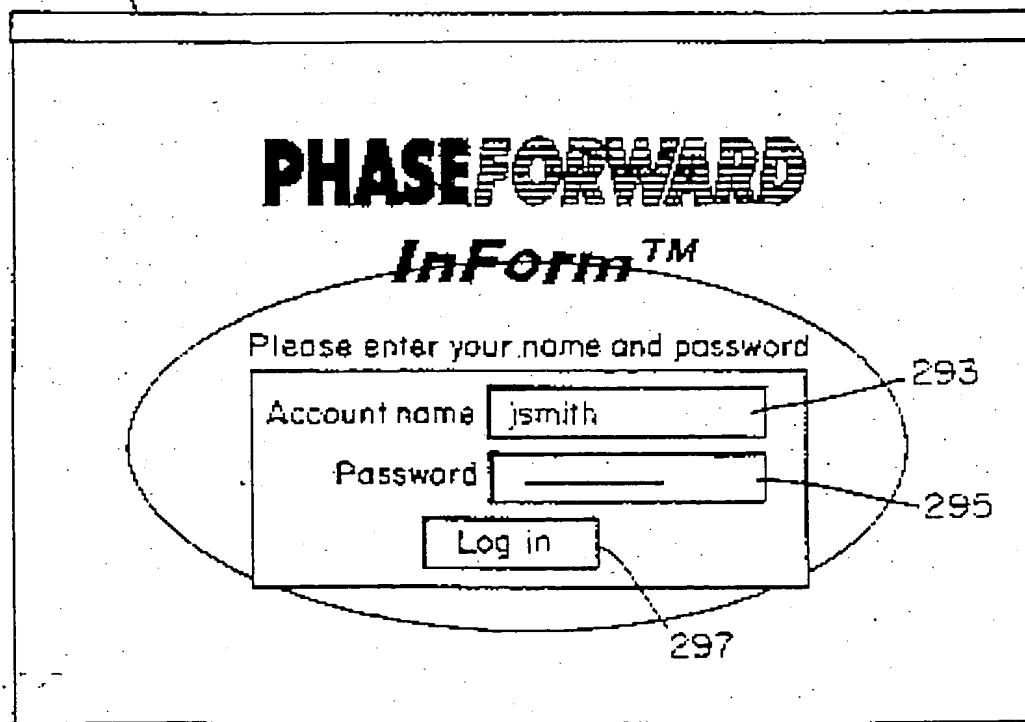


FIG. 6

6/17

100

PF-105 Clinical Drug Trial

Study News

We are pleased to announce that we have initiated the first ever clinical trial to test the safety and efficacy of a new mechanism of action for hypertension. The trial will involve approximately 1000 patients across 10 sites.

Alerts

No alerts are currently available.

Enrollment

No enrollment is currently available.

Study Data Process

No data is currently available.

CRFs to Complete

Patients	303
Intervention	305
Visit Schedule	307

JPH/Q: Wk-4 Dem

JPH/Q: Wk-4 ECG

JPH/Q: T & E Sched

Site QI GRBs

Patient No. Visit Week-4 Go

JENIFER SMITH, R.N.
Clinical Research Coordinator

Home **Help** **Logout**

Enrollment

Visits

Queries

Status

Documents

FIG. 7

9/17

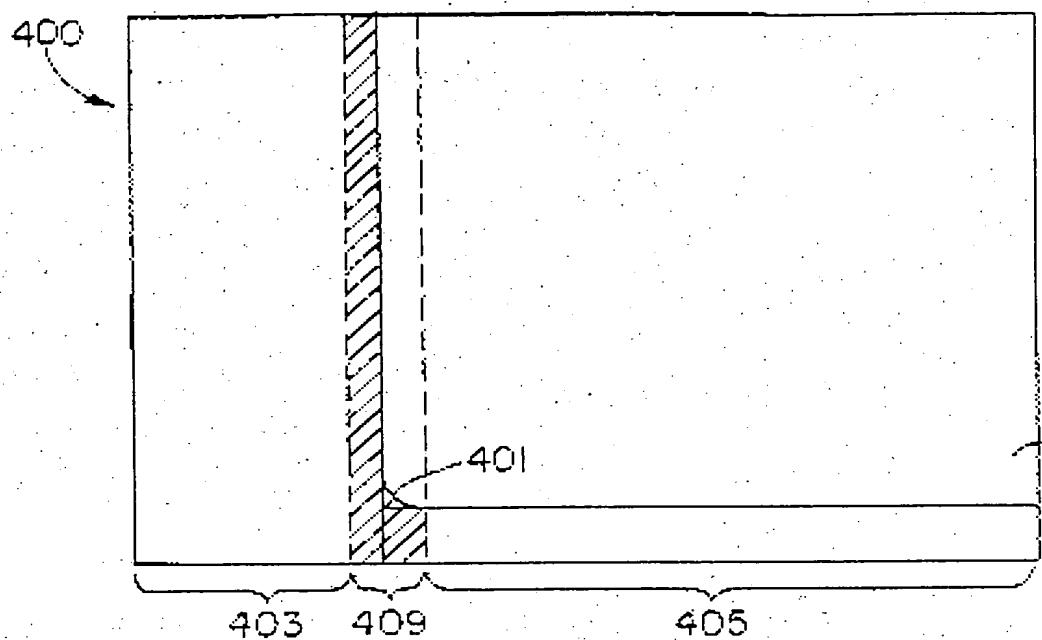


FIG. 8

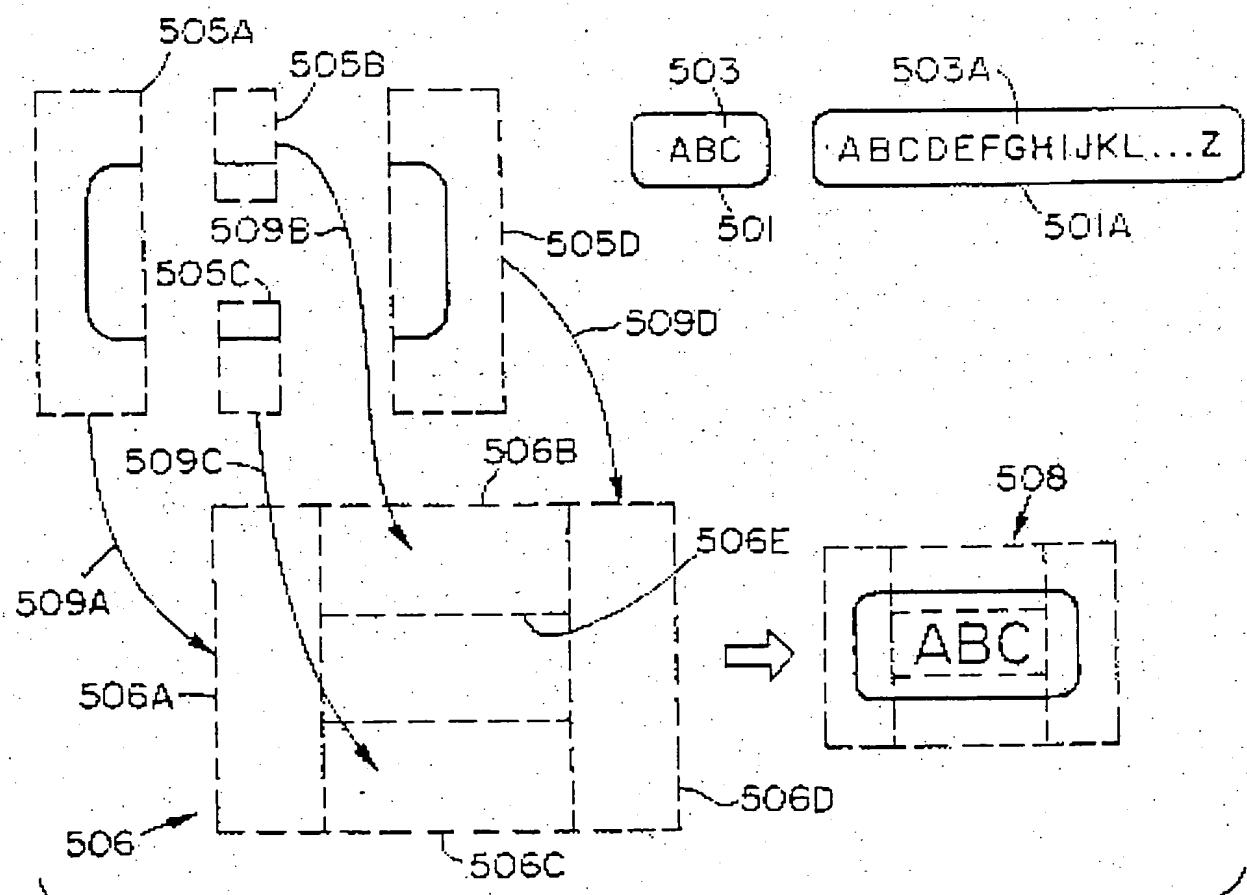


FIG. 9

10/17

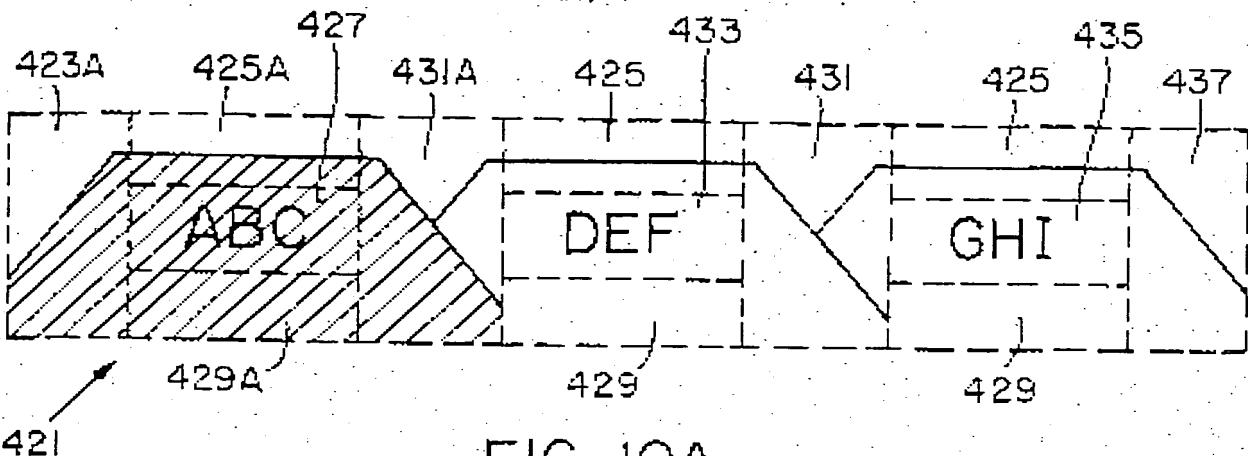


FIG. 10A

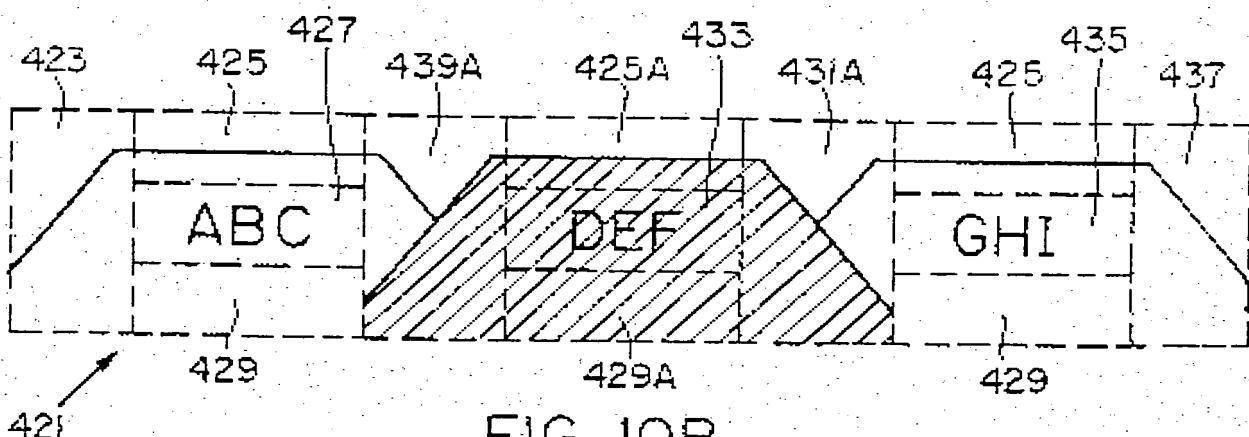


FIG. 10B

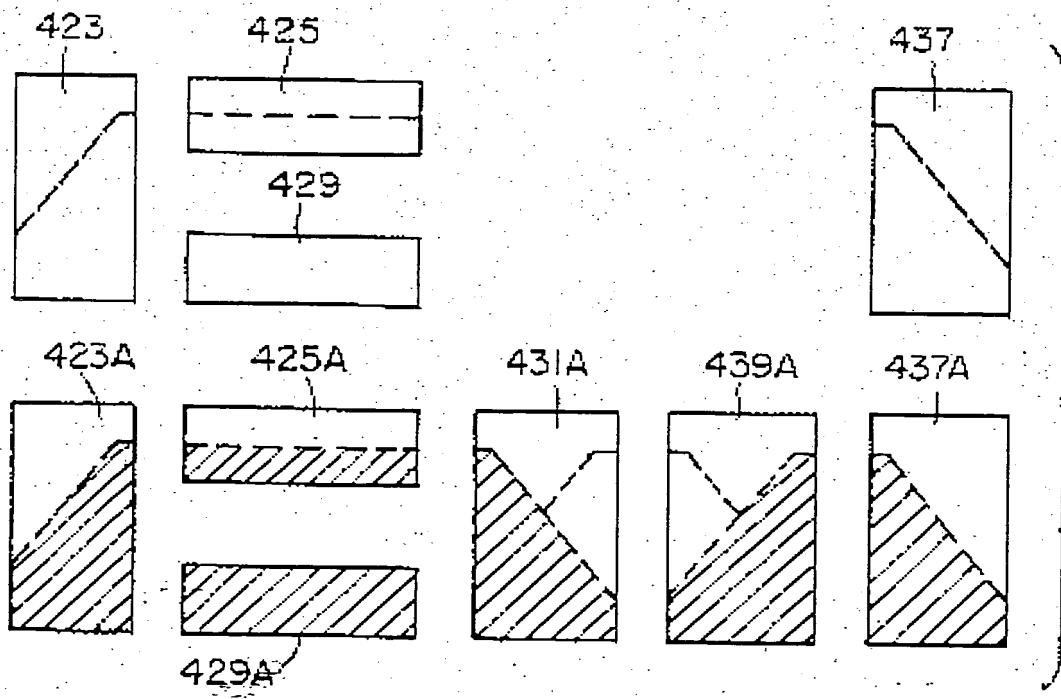


FIG. 10C

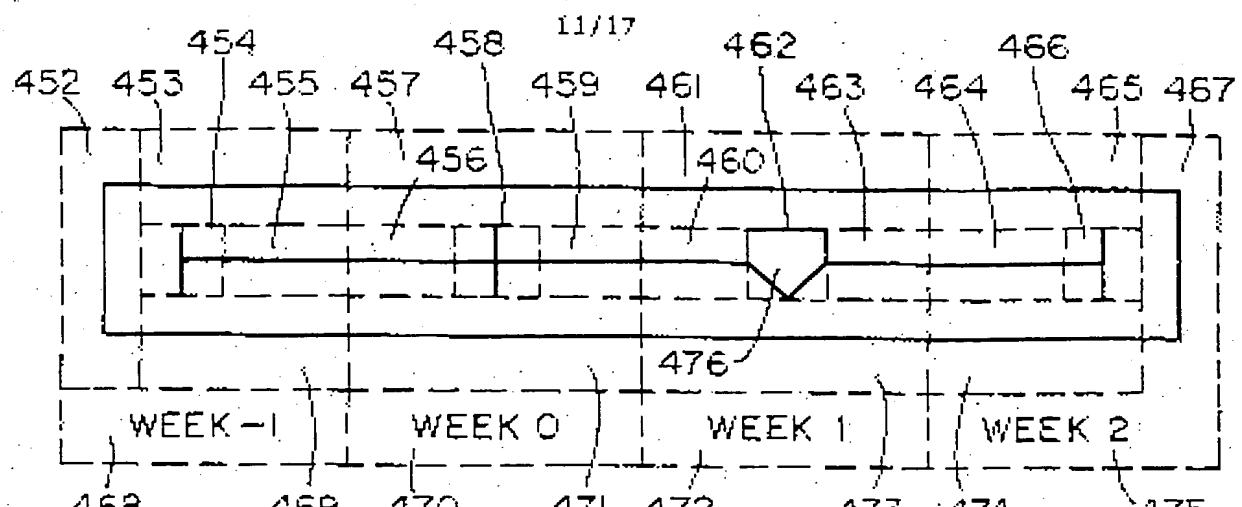


FIG. 11A

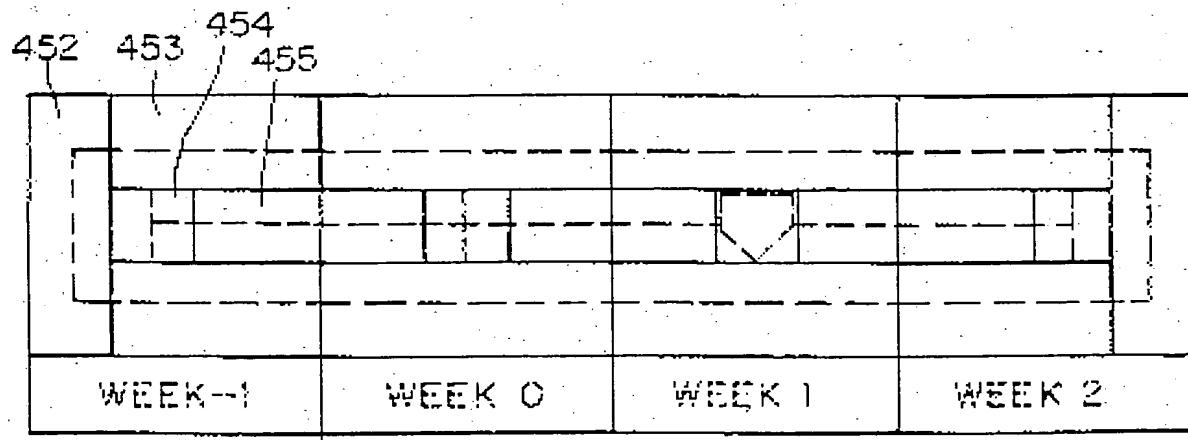


FIG. 11B

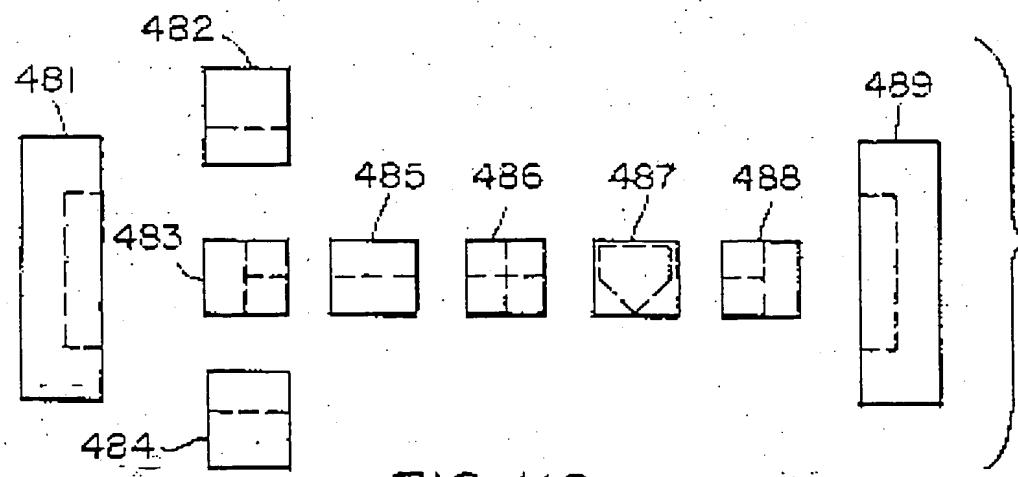


FIG. 11C

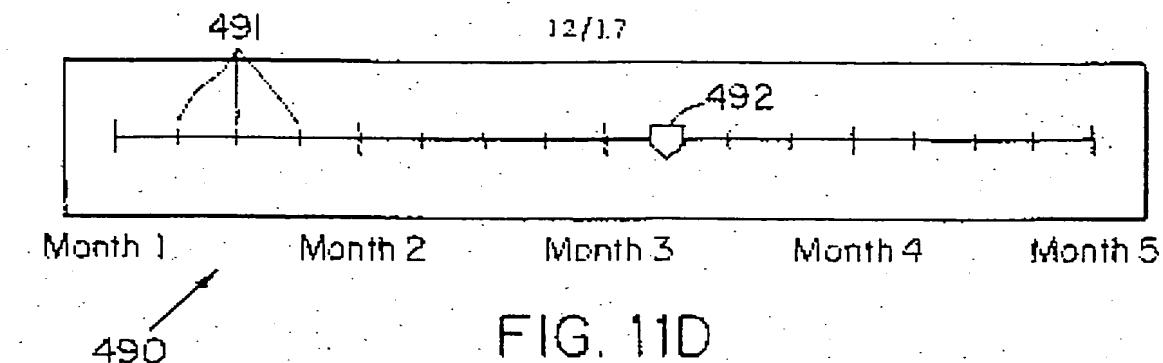


FIG. 11D

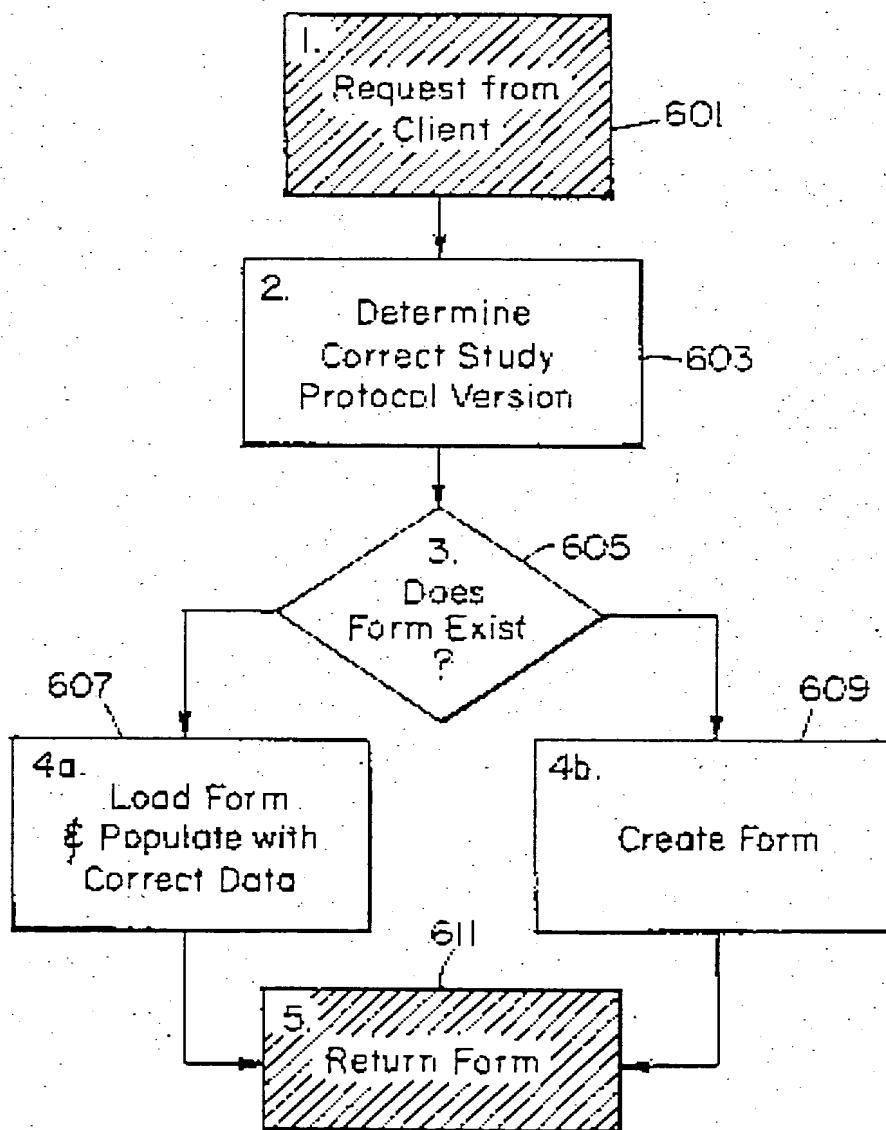


FIG. 12A

13/17

5

82

62

PROTOCOL VERSION 1

1 Date of Assessment:	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
2 Blood Pressure Reading 1:	<input type="checkbox"/>	<input checked="" type="checkbox"/>	/	<input checked="" type="checkbox"/> Mm Hg
3 Blood Pressure Reading 2:	<input type="checkbox"/>	<input checked="" type="checkbox"/>	/	<input checked="" type="checkbox"/> Mm Hg

FIG. 12B

14/17

२

PROTOCOL VERSION 2

1 Date of Assessment:	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/>
2 Blood Pressure Reading 1:	<input type="checkbox"/> / <input type="checkbox"/>	<input type="checkbox"/> / <input type="checkbox"/>	Mm Hg
3 Blood Pressure Reading 2:	<input type="checkbox"/> / <input type="checkbox"/>	<input type="checkbox"/> / <input type="checkbox"/>	Mm Hg
4 Blood Pressure Reading 3:	<input type="checkbox"/> / <input type="checkbox"/>	<input type="checkbox"/> / <input type="checkbox"/>	Mm Hg

FIG. 12C

15/17

Help Link BO!



Jennifer Smith, RN
Clinical Research Coordinator

Home | Help | Logout

Enrollment

Visits

Queries

Status

Documents

JPH/ON/Wk-4 Dem
JPH/ON/Wk-4 ECG
JPH/OT/T\$ E Schc
Site DI GRBs

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	
IF	DEMA	HH	SS	PE	VS/EP	ECG/EXP	LAB	CM

Demographics Ready for SDV Patient: JPK Patient No: DI-COI

1. Gender: Male Female

2. Date of Birth: Feb 19 1984

3. Past/Ethnic Origin: Black Other (Specify) _____

4. Height: 66 in. Dem

5. Weight: 145 lb. Dem

6. Frame: Medium

7. Calculated weight variance from avg. % Above/Below

Smoking History

7. Has patient ever smoked? Yes No Not Done
Indicates that the patient smokes cigarettes in item 9. Please check that this is the correct answer to item 7 for patient ever smoked?

8. If the patient has ever smoked, has the patient quit smoking? Yes No Not Done

9. If the patient currently smokes, Cigarettes Cigars Pipe Not Done
The patient smokes:

10. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: Unknown Not Done

Submit **Cancel**

FIG. 13A

Context Sensitive Help BO4

Help Window BO3



Jennifer Smith, RN
Clinical Research Coordinator

Home | Help | Logout

Enrollment

Visits

Queries

Status

Documents

JPH/ON/Wk-4 Dem
JPH/ON/Wk-4 ECG
JPH/OT/T\$ E Schc
Site DI GRBs

Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	
IF	DEMA	HH	SS	PE	VS/EP	ECG/EXP	LAB	CM

Demographics Ready for SDV Patient: JPK Patient No: DI-COI

Demographics

Item 4 Height

- Height must be measured
- Measure height with shoes off
- Report height in either inches or centimeters. (The entry will be converted to the desired units for report purposes.)

Item 5 Weight

- Use pounds or kilograms for measurement
- Convert to kilograms if the last digit is a decimal.

Item 6 Frame

- Use the following frame size measurements
- Use the same frame size throughout the study.

Smoking History

Protocols **Study Guide** **Help** **Investigator Brochure** **Close**

9. If the patient currently smokes, Cigarettes Cigars Pipe Not Done
The patient smokes:

10. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: Unknown Not Done

Submit **Cancel**

FIG. 13B

Help Button
807

16/17

251A

Demographics

1. Gender:	Male	Female		
2. Date of Birth:	Feb 19	19	1984	19
3. Race/Ethnic Origin:	Brown	White	Other	Unknown
4. Height:	5'6"	5'10"	6'0"	
5. Weight:	145	160	170	
6. Ethnic:	White			
Calculated weight reference from age:				
Smoking History				
1.	Has patient ever smoked P. Other <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes Done Has patient ever smoked cigarettes? Please check one of the following boxes or type the patient's name below?			
2.	If the patient has ever smoked, has the patient quit smoking? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Done			
3.	If the patient currently smokes, <input checked="" type="checkbox"/> Cigarettes <input type="checkbox"/> Pipes <input type="checkbox"/> Not Done The patient smokes: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not Done			
4.	If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: <input type="checkbox"/> 1 <input checked="" type="checkbox"/> Unknown <input type="checkbox"/> Not Done			

Submit **Cancel**

JPH/OfWk-4 Dem
JPH/OfWk-4 ECG
JPK/OfTBE Sched
Site Of GRBs

FIG. 13C

810

811

Help Window
809

Demographics

Phase Forward Help - Microsoft Internet Explorer

Contents / Index

Basics

- How do I log in?
- Decision to use Clinical Trials Information Environment
- What are my rights as a participant?

Introducing CTE

- What is CTE?
- Who is in CTE?
- What is the CTE environment?

Navigating

- Overview, Informed Consent
- Managing patient data
- Monitoring Your Monitoring

Protocols **Study Guide** **Help** **Investigator Brochure** **Close**

10. If the patient has ever smoked cigarettes, enter the average number of packs smoked per day: 1 Unknown Not Done

Submit **Cancel**

JPH/OfWk-4 Dem
JPH/OfWk-4 ECG
JPH/OfTBE Sched
Site Of GRBs

805

FIG. 13D

81F

17/17

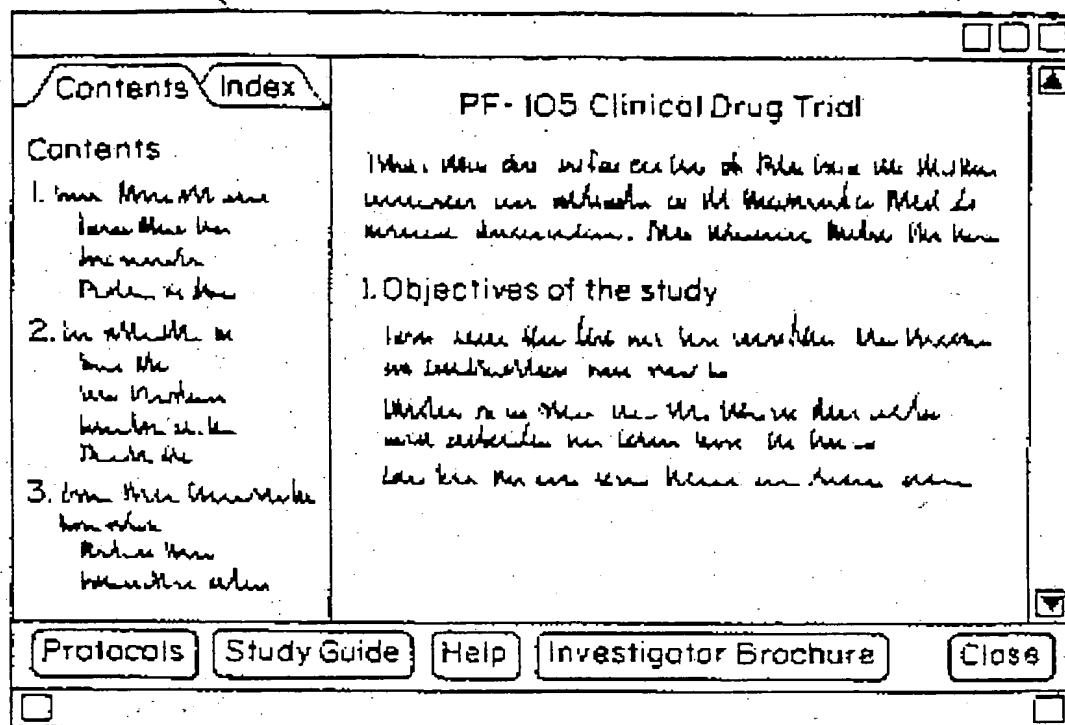


FIG. 13E

812

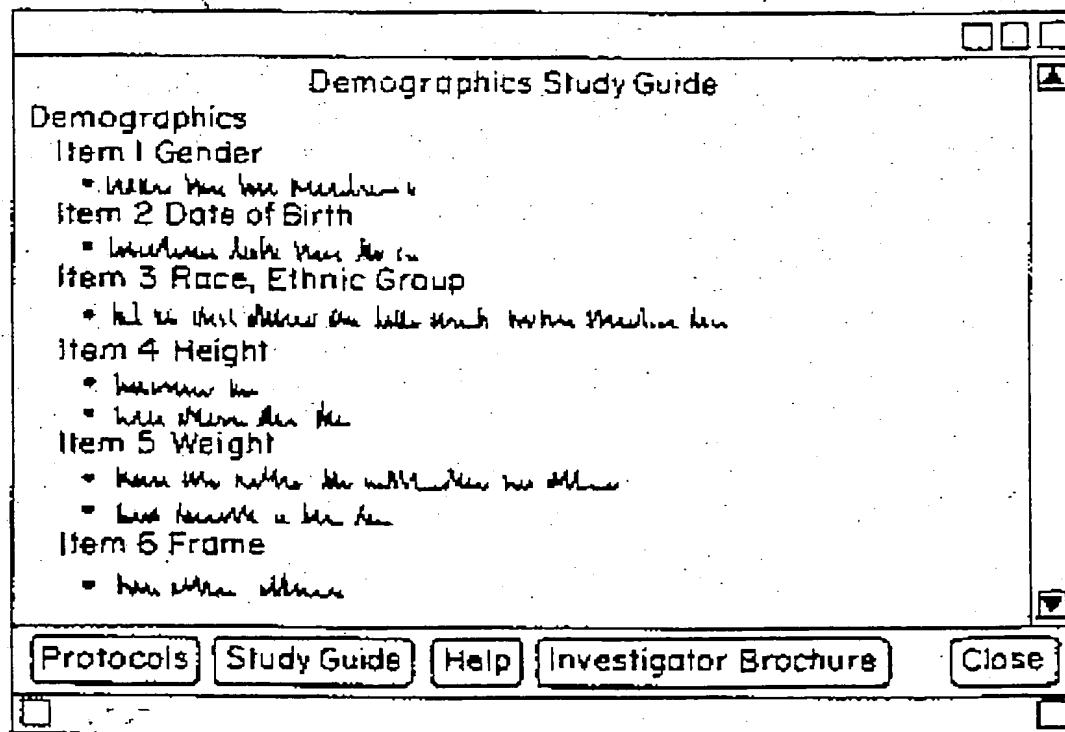
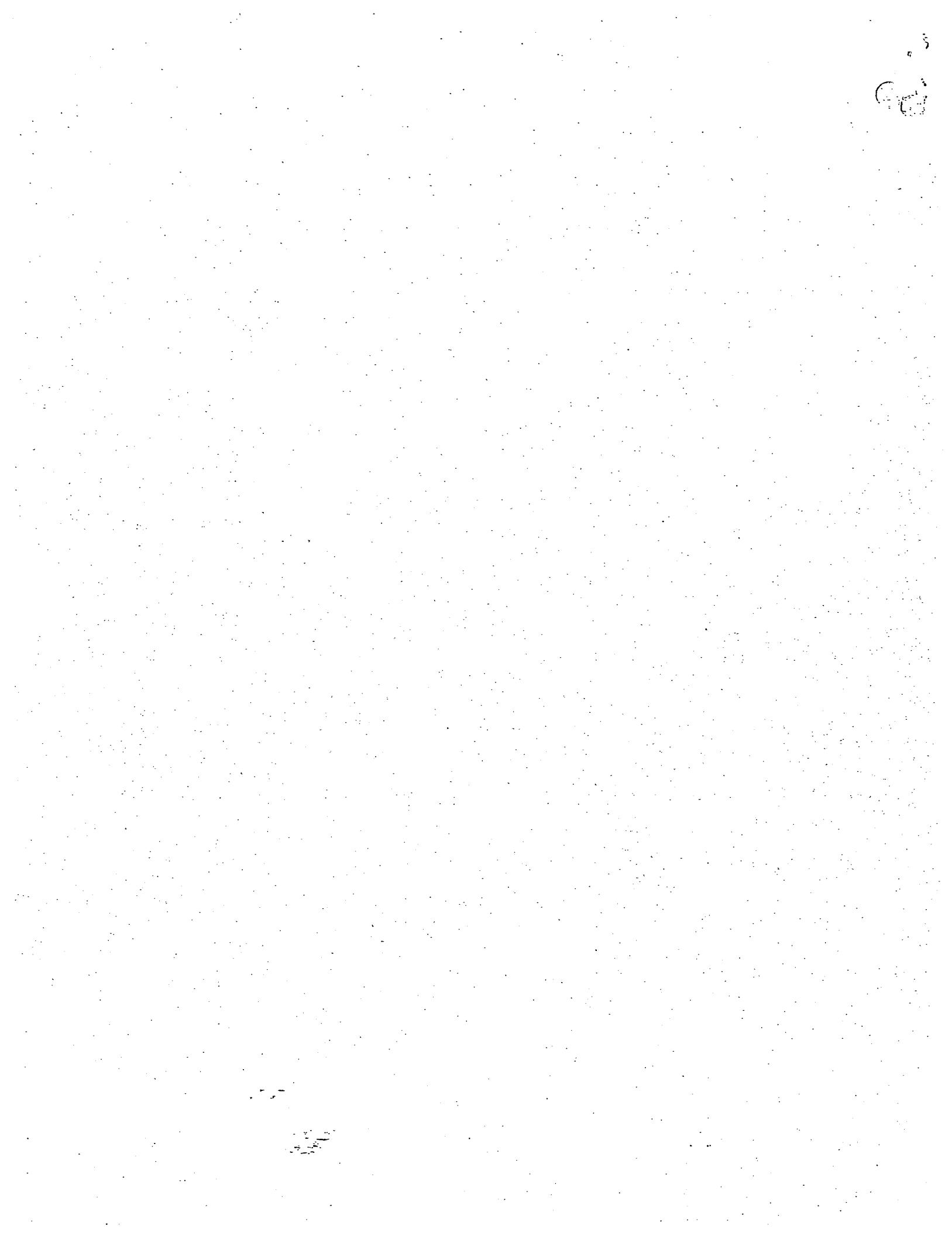


FIG. 13F





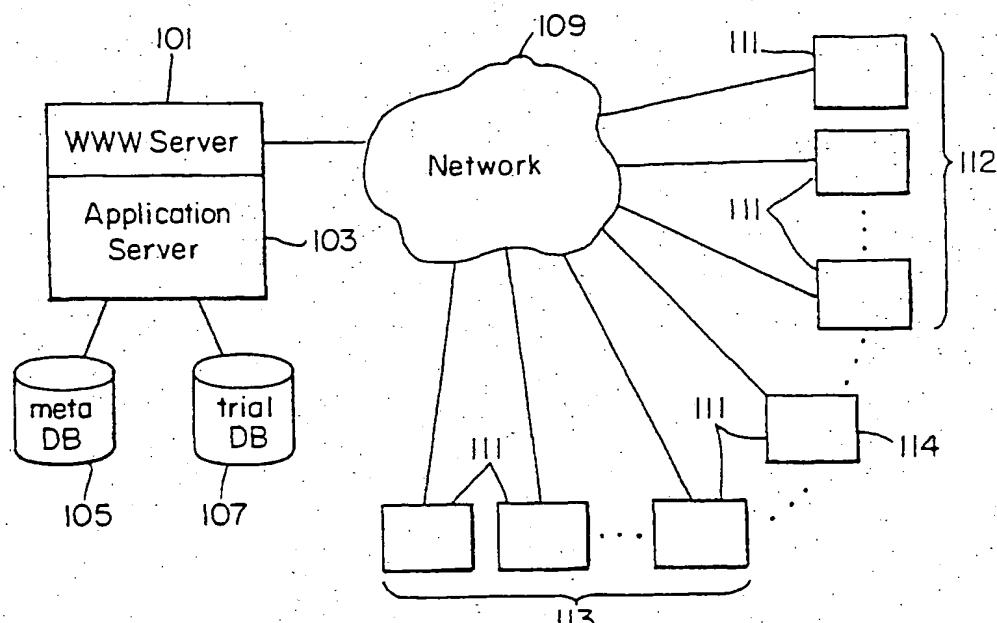
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : G06F 19/00, 9/44	A3	(11) International Publication Number: WO 99/63473 (43) International Publication Date: 9 December 1999 (09.12.99)
<p>(21) International Application Number: PCT/US99/12406</p> <p>(22) International Filing Date: 3 June 1999 (03.06.99)</p> <p>(30) Priority Data: 09/092,441 5 June 1998 (05.06.98) US</p> <p>(71) Applicant: PHASE FORWARD INC. [US/US]; 51 Winchester Street, Newton, MA 02461 (US).</p> <p>(72) Inventors: BLEICHER, Paul, A.; 174 Mt. Vernon Street, Newton, MA 02165 (US). STAMOS, Nicholas; 22 Jeannette Avenue, Belmont, MA 02478 (US). KLOFFT, Jeffrey, P.; 33 Hamilton Circle, Marlborough, MA 01752 (US). DALE, Richard, M.; 117 Russell Street, Newton, MA 02165 (US).</p> <p>(74) Agents: SMITH, James, M. et al.; Hamilton, Brook, Smith & Reynolds, P.C., Two Militia Drive, Lexington, MA 02421 (US).</p>		<p>(81) Designated States: DE, GB, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p> <p>(88) Date of publication of the international search report: 27 January 2000 (27.01.00)</p>

(54) Title: CLINICAL TRIAL DATA MANAGEMENT SYSTEM AND METHOD

(57) Abstract

A system and method for managing clinical trial data includes dynamically generating, at a server, a data entry form to be displayed at a client. The data entry form is generated dynamically in a SGML-derived language. Control elements within the form comprise images which are used to construct the control elements and larger controls. The form is generated from a protocol database and a context received from the client, is populated from the data database, and is published to the client. Templates based on the protocol database comprise several frames including intermediate frames for displaying frame borders which are non-horizontal



and non-vertical. If the trial protocol changes during a trial, the generated form is based on the protocol version active at the time data was entered into the form. Inadvertent use of the application is discouraged requiring an authentication procedure and displaying a picture of the authenticated user. Furthermore, help is provided by creating a link between the text of each question and information about the question. The source of help may be any or all of a protocol document, an investigative brochure, and a study guide. In addition, a user, upon logging in, is presented with a dashboard screen which provides information or links to information such as trial-related news, alerts, statistical information, progress reports and a list of work to be completed.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTERNATIONAL SEARCH REPORT

Inte
onal Application No
PCT/US 99/12406

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G06F19/00 G06F9/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KIUCHI T ET AL: "Automated generation of a World Wide Web-based data entry and check program for medical applications" COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE, FEB. 1997, ELSEVIER, NETHERLANDS, vol. 52, no. 2, - February 1997 (1997-02) pages 129-138, XP002123139 ISSN: 0169-2607 the whole document -/-	1-56

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the International filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "T" document published prior to the International filing date but later than the priority date claimed

"T" later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the International search

18 November 1999

Date of mailing of the International search report

03/12/1999

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk.
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Fonderson, A

INTERNATIONAL SEARCH REPORT

Int'l Application No.
PCT/US 99/12406

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	KELLY M A ET AL: "The Internet and randomised controlled trials" INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS, IR, ELSEVIER SCIENTIFIC PUBLISHERS, SHANNON, vol. 47, no. 1-2, - 1997 page 91-99 XP004107516 ISSN: 1386-5056 the whole document	1-56
A	"MULTI-STATE BUTTON MANIPULATION USING A SINGLE GRAPHIC" IBM TECHNICAL DISCLOSURE BULLETIN, US, IBM CORP. NEW YORK, vol. 38, no. 4, page 585-587 XP000516262 ISSN: 0018-8689 the whole document	5, 24, 25, 28-31, 35, 36, 43, 44, 46, 47, 50, 53, 54
A	ANONYMOUS: "Efficient 3D Buttons in Dynamic Hyper Text Markup Language Pages" IBM TECHNICAL DISCLOSURE BULLETIN, vol. 41, no. 1, pages 695-698, XP002123140 New York, US the whole document	5, 24, 25, 28-31, 35, 36, 43, 44, 46, 47, 50, 53, 54
A	GIRGENSOHN A ET AL: "Seamless integration of interactive forms into the Web" COMPUTER NETWORKS AND ISDN SYSTEMS, NL, NORTH HOLLAND PUBLISHING. AMSTERDAM, vol. 29, no. 8-13, page 1531-1542 XP004095347 ISSN: 0169-7552 the whole document	7-17, 42
A	NETSCAPE COMMUNICATIONS CORP.: "NetHelp" NETHELP RELEASE 1.0 SDK DOCUMENTATION, 'Online!' - August 1996 (1996-08) pages 1-14, XP002071214 USA Retrieved from the Internet: <URL: http://home.netscape.com/eng/help/sdk1/sdksite.htm > 'retrieved on 1998-07-10' the whole document	7-17, 42